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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/297,652	07/08/1999	RICHARD EDWARD THOMAS	MIJ-001US	1100

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/297,652

Applicant(s)

THOMAS, RICHARD EDWARD

Examiner

Barbara P Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) ____.   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

**First Office Action on the Merits of a Continued Prosecution Application**

***Continued Prosecution Application***

1. The request filed on January 11, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/297,652 is acceptable and a CPA has been established. An action on the CPA follows.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejections of claims 1-37 as indicated below are of record (see Paper No. 9).

*29, 32, 33, 35-38,*

***Claim Rejections - 35 USC § 102***

4. The rejection of claims 1-5, 7-8, 11-15, 18, 21, 22, 27 and 29-37 under 35 USC 102(b) over Papandrea (AU-34351/89) is maintained.

Papandrea teaches a composition comprising a gold compound and a corticosteroid for the treatment of local or systemic inflammatory conditions (see the entire article; especially page 6, lines 8-14 and page 11, example 2; claims 6-11 and 18). The reference teaches (a) gold compounds such as aurothiomalate, aurothioglucose and auranofin (page 1, Background, lines 1-11; pages 6-8; page 11, example 2); (b) corticosteroid such as betamethasone dipropionate (page 8, lines 5-8; page 11, example 2); and (c) the synergistic effect between auranofin and

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corticosteroids as well as the concomitant or sequential use of the compounds (page 17, lines 9-16). The composition and method of use taught by the reference are encompassed by the instant claims.

29, 32, 33, 35-38  
5. The rejection of claims 1-5, 7-8, 11-15, 18, 21, 22, 27 and 29-37 under 35 USC 102(e) over Papandrea (US 5,527,779) is maintained.

Papandrea teaches a composition comprising a gold compound and a corticosteroid for the treatment of local or systemic inflammatory conditions (see the entire article; especially col. 2, lines 51-54; col. 3, lines 4-11; col. 5, example 2; claims 1-15). The reference teaches (a) gold compounds such as aurothiomalate, aurothioglucose and auranofin (col. 1, lines 14-25; col. 3, lines 21-59; col. 5, example 2); (b) corticosteroid such as betamethasone dipropionate (col. 3, lines 60-63; col. 5, example 2); and (c) the synergistic effect between auranofin and corticosteroids as well as the concomitant or sequential use of the compounds (col. 8, lines 6-12). The composition and method of use taught by the reference are encompassed by the instant claims.

**Claim Rejections - 35 USC § 103**

29-47.  
6. The rejection of claims 1-37 under 35 USC 103(a) over Papandrea (AU-34351/89 or US 5,527,779) is maintained.

Papandrea teaches a composition comprising a gold compound and a corticosteroid for the treatment of local or systemic inflammatory conditions (see the

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entire articles; especially **AU 34351**, page 6, lines 8-14 and page 11, example 2; and '779, col. 2, lines 51-54; col. 3, lines 4-11; col. 5, example 2; claims 1-15). The reference teaches (a) gold compounds such as aurothiomalate, aurothioglucose and auranofin (**AU 34351**, page 1, Background, lines 1-11; pages 6-8; page 11, example 2 and '779, col. 1, lines 14-25; col. 3, lines 21-59; col. 5, example 2); (b) corticosteroid such as betamethasone dipropionate (**AU 34351**, page 8, lines 5-8; page 11, example 2 and '779, col. 3, lines 60-63; col. 5, example 2); and (c) the synergistic effect between auranofin and corticosteroids as well as the concomitant or sequential use of the compounds (**AU 34351**, page 17, lines 9-16 and '779, col. 8, lines 6-12).

The instant claims (see claims 15, 16, 17, 35 and 36) differ from the references by reciting additional corticosteroids not exemplified by the cited prior art. However, the compounds recited by the instant invention are well known in the art, and, thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize any corticosteroid, including those of the instant claims, in the composition taught by Papandrea with the reasonable expectation that the composition would be useful as taught by the prior art.

Claim 6, further differs from the references by reciting the administration of at least two corticosteroids.

Claims 10, 16 and 17 further differ from the references by reciting various routes of administration.

However, (a) it is known in the art that corticosteroids and gold compounds are useful in the treatment of rheumatoid arthritis, dermatitis and psoriasis (see for example,

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US patents 3,937,822; 4,119,723 and 4,267,192); (b) it is obvious to combine two or more compounds or composition taught by the prior art to be useful for the same purpose to form a third composition that is be used for the very same purpose; In re Kerkhoven, 205 USPQ 1069 (CPA 1980) and (c) it is within the level of skill of one having ordinary skill in the pharmaceutical art to make various pharmaceutical preparations for administration by different routes. Therefore, the combination of one or two corticosteroids with a gold compound for the treatment of an immune-mediated disorder, such as rheumatoid arthritis, dermatitis and psoriasis, would have been obvious to one having ordinary skill in the art at the time of the invention and the administration of the composition by the recited routes of administration is within the level of skill of the ordinary artisan and, thus, is prima facie obvious.


### ***Telephone Inquiry***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
(Barbara P Badio, Ph.D.)  
Primary Examiner  
Art Unit 1616

BB  
February 4, 2002